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EXAMINER	
ART UNIT	PAPER NUMBER
	4

DATE MAILED: 05 19 86

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

[X] This application has been examined [ ] Responsive to communication filed on _____ [ ] This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. [X] Notice of References Cited by Examiner, PTO-892.
2. [ ] Notice re Patent Drawing, PTO-948.
3. [X] Notice of Art Cited by Applicant, PTO-1449
4. [ ] Notice of informal Patent Application, Form PTO-152
5. [ ] Information on How to Effect Drawing Changes, PTO-1474
6. [ ] _____

Part II SUMMARY OF ACTION

1. [X] Claims 1-16 are pending in the application.
   Of the above, claims 5-16 are withdrawn from consideration.
2. [ ] Claims _____ have been cancelled.
3. [ ] Claims _____ are allowed.
4. [X] Claims 1-4 are rejected.
5. [ ] Claims _____ are objected to.
6. [X] Claims 1-16 are subject to restriction or election requirement.
7. [ ] This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
8. [ ] Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
9. [ ] The corrected or substitute drawings have been received on _____. These drawings are [ ] acceptable; [ ] not acceptable (see explanation).
10. [ ] The [ ] proposed drawing correction and/or the [ ] proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been [ ] approved by the examiner. [ ] disapproved by the examiner (see explanation).
11. [ ] The proposed drawing correction, filed _____, has been [ ] approved. [ ] disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.
12. [X] Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has [X] been received [ ] not been received
    [ ] been filed in parent application, serial no. _____; filed on _____
13. [ ] Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. [ ] Other

EXAMINER'S ACTION

15. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to factor IX protein (I), classified in Class 530, subclass 384.

II. Claims 5-16, drawn to a process of preparing factor IX protein (II), classified in Class 435, subclass 172.3.

16. The inventions are distinct, each from the other, because of the following reasons:

Inventions II and I are related as process of making and product made.

The inventions are distinct if either (1) the process as claimed can be used to make another and materially different product, or (2) the product as claimed can be made by another and materially different process. MPEP 806.05(f).

In this case, the product as claimed can be made by a materially different process, such as via purification of naturally produced factor IX from plasma sources.

17. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because of their recognized divergent subject matter restriction for examination purposes as indicated is proper.

18. During a telephone conversation with Mr. Mitchard on March 31, 1988 a provisional election was made with traverse to prosecute the invention of Group I, the factor IX protein, claims 1-4. Affirmation of this election must be made by applicant in responding to this Office action. Claims 5-16 are withdrawn from further consideration by the examiner as being drawn to a nonelected invention. See 37 CFR 1.142(b).

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless-
>
> (a)the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

21. Claims 1-4 are rejected under 35 U.S.C. 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Osterud et al, Schwinn et al, Suomela et al or Anderson et al.

Factor IX, or Christmas Factor is well known in the art, as are conventional means of producing said factor. The factor IX protein claimed by applicant is the same protein known in the art, even though the method used to produce the protein is not the same as those shown in the prior art. Note M.P.E.P. 706.03(e).

The disclosure of Osterud et al shows the isolation and purification to homogeneity of factor IX. Note the extensive analysis and comparison of the human to bovine species, and the results of assessing the activity of the purified human factor IX presented in table 1. Andersson et al show the production of human factor IX suitable for human therapeutic use via several procedures. Note examples 9 through 16 especially. Schwinn et al also disclose a procedure for production of a purified human factor IX preparation which is sterile and can be used in the treatment of blood clotting disorders in humans. Suomela shows production of highly purified human factor IX.

In each of the cited references, human factor IX in a substantially purified form is disclosed. The factor IX claimed by applicant is inherently the same protein. The presence of poxvirus contaminants in the factor IX compositions disclosed by the prior art is believed to be insignificant in view of the methods used to produce said compositions, particularly with respect to the chromatographic purification steps shown in each disclosure. The burden of proving the factor IX claimed is not inherently the same as the factor IX shown in the cited art, and therefore is distinct and unobvious, is shifted to the applicant.

21A. Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by Anson et al (Nature, June 1985).

The cited reference is valid prior art under 35 USC 102(a). Note especially the last paragraph on page 685 of this reference. The foreign priority documents relied upon by applicants do not enable the current claims 1-4. No mention of specific clotting activity as currently claimed can be found. The priority documents do not enable the current claims, and therefore cannot be used to base a claim for priority.

The biologically active recombinant factor IX of Anson et al anticipates claims 1-4.

22. Claims 1 and 2 are rejected under 35 U.S.C. 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Fujikawa et al.

Fujikawa et al disclose a procedure for the production of high purity bovine factor IX. Claims 1 and 2 of applicant encompass factor IX from any source including bovine. The method used to produce factor IX does not render the protein patentably distinct over bovine factor IX disclosed by Fujikawa et al, because the proteins have the same physical properties (i.e. amino acid composition, sequence, molecular weight and activity). Note M.P.E.P. 706.03(e). The burden of proving the claimed factor IX distinct and unobvious over the cited art is shifted to applicant.

23. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to provide an enabling disclosure .

Claims 1 and 4 recite a characteristic that is dependant on a specific monoclonal antibody (i.e. specific activity). Because of this recitation, evidence must be submitted showing that the monoclonal antibody is readily available to the public. Applicant must meet this requirement either by fulfilling the hybridoma deposit according to M.P.E.P. 608.03(p) or by showing that the particular hybridoma is known and available.

24. Claims 1 and 4 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the above objection to the specification.

25. Claims 1-4 are rejected under 35 U.S.C. 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims dependent on "specific activity" are confusing because the terms "clotting activity" and "antigenic concentration" are not readily quantifiable terms as presented. The reference to a printed publication describing the clotting assay technique used by applicant should be summarized as the content of this reference is an essential aspect used in defining the claimed product.

Claim 2 is indefinite because the "biologically active factor IX protein" and "precurser factor IX" are not clearly distinguished from each other. Is the precurser protein factor IX which has not been subjected to the vitamin K dependent post-translational GEA modification? This is unclear.

26. The art made of record but not used in basing a rejection is of interest.

27. The incorporation of essential material by reference to a foreign application or foreign patent or to a publication inserted in the specification is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or applicant's attorney or agent, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. In re Hawkins, 486 F.2d 569, 179 USPQ 157; In re Hawkins, 486 F.2d 579, 179 USPQ 163; In re Hawkins, 486 F.2d 577, 179 USPQ 167.

28. Any inquiry concerning this communication should be directed to Jeff Kushan at telephone number 703-557-0664.

Kushan:bjk
4/25/88
Retype: 4/27/88; 5/2/88

HOWARD E. SCHAIN
PATENT EXAMINER
GROUP 180 - ART UNIT 183